



Attorney Docket No: COUL-005/04US

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By:

Sandra Baldwin

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Stewart M. Kroll, et al.

Serial No.: 09/326,502

Examiner: J. Lundgren

Filed: June 4, 1999

Art Unit: 1631

For: PATIENT-SPECIFIC DOSIMETRY

Commissioner for Patents
Washington, D.C. 20231

RESPONSE

In response to the Official Action of September 8, 2000, Applicant has made an election of claims, with traverse. Applicant is also taking this opportunity to amend claim 1.

AMENDMENTS

Please amend claim 1 as follows:

- Sub 21*
a1
1. (Amended) A method of establishing a patient-specific optimally effective dose for administration of a radiopharmaceutical to a patient, the method comprising:
determining a maximum tolerated dose for the radiopharmaceutical [for the patient population];

At
conclusion

determining a desired total body dose of the radiopharmaceutical for the patient;
determining the clearance profile for the radiopharmaceutical or a radiopharmaceutical analog;
determining the patient's mass and maximum effective mass;
selecting the lower of the patient's mass and maximum effective mass;
determining the activity hours for the radiopharmaceutical or radiopharmaceutical analog based on the lower of the patient's mass or maximum effective mass and the desired total body dose;
[administering a tracer dose of the radiopharmaceutical or the radiopharmaceutical analog to the patient;]
determining the residence time [for the] of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient, the residence time being correlated to the clearance profile; and
establishing the optimally effective dose of the radiopharmaceutical for the patient by solving for therapeutic dose in the following equation:

$$\text{therapeutic dose} = \frac{\text{Activity Hours}}{\text{Residence time}} \times \frac{\text{desired total body dose}}{\text{maximum tolerated dose.}}$$

REMARKS

Claim 1 has been amended to remove an unnecessary limitation and to improve clarity of the claim language. More specifically, in the step of determining a maximum tolerated dose for the radiopharmaceutical, the limitation "for the patient population" has been deleted. Support for this amendment exists in the specification at page 8, wherein establishing a maximum tolerated dose is described with reference to other than a specific patient population. Claim 1 has also been amended by more clearly describing the step of determining the residence time. This amendment finds support in original claim 20 and at pages 21-22 of the specification. No new matter has been added by such amendments and the Examiner is respectfully requested to enter them.